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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,263	12/21/2001	Kimberly Marie Geiser	17,036	3098

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EXAMINER

STEPHENS, JACQUELINE F

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/027,263

Applicant(s)

GEISER ET AL.

Examiner

Jacqueline F Stephens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 10, 11, 13-15, 17-19, 33, 37, 41, 42, 46, 48 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12, 16, 20-32, 34-36, 38-40, 43-45, 47, 49-51 and 53-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement..

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/19/04, 2/14/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 1/27/03, 9/18/02, 9/3/02</u> . |

DETAILED ACTION

Election/Restrictions

1. Claims 1-55 are pending in the present application. Applicant's election without traverse of claims 1-9, 12, 16, 20-32, 34-36, 38-40, 43-45, 47, 49-51, 53, 54, and 55 in the reply filed on 4/27/04 is acknowledged.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 7, 12, 22, 26, 31, 32, 34, 42-45, 50, 51, 54, and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Lucas AU 199941153.

As to claims 1, 3, 31, 32, 42, 43, 50, and 51, Lucas discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon and the therapeutic agent is a botanical (page 2, lines 1-3; page 3, lines 18-23 and Figures 1 and 2). The therapeutic agent is carried into the body by means of the tampon surface.

As to claim 21, Lucas discloses the therapeutic agent is capable of treating dysmenorrhea (page 4, lines 7-10).

As to claims 2, 7, 44, and 45, Lucas discloses the therapeutic agent is applied to the surface of the tampon body (page 3, lines 18-23 and Figures 1 and 2).

As to claim 4, the cover of Lucas is inherently liquid-permeable as the tampon is configured to absorb fluids.

As to claim 12, Lucas discloses *rehmannia glutinosa* may be used instead of licorice (page 7, lines 1-4), which indicates licorice may alternatively be used.

As to claims 22 and 26, Lucas discloses the therapeutic agent is a powder, which is also a solid (page 2, lines 12-14).

As to claim 34, Lucas discloses the therapeutic agent is applied to the surface of the tampon body. The limitation of the agent being applied before the body is constructed is directed to a process of making the article. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). MPEP 2113.

As to claim 54, Lucas discloses a method of treating a woman via the vaginal epithelium comprising exposing the epithelium to a formulation including a therapeutic agent residing on a tampon (page 2, lines 1-3; page 3, lines 18-23 and Figures 1 and 2). The therapeutic agent is carried into the body by means of the tampon surface. Lucas

discloses rehmanna glutinosa may be used instead of licorice (page 7, lines 1-4), which indicates licorice may alternatively be used.

As to claim 55, the method includes a therapeutic agent that is a combination of a botanical and a beneficial agent from the claimed types of beneficial agents (page 3, lines 4-17).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 20, 21, 23-25, 27, 39, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lucas in view of Harrison et al. USPN 6086909.

As to claims 20, 21, 23-25, 27, 38, 39, and 40 and 27 Lucas discloses the present invention substantially as claimed. However, Lucas does not disclose the various forms of the therapeutic agent. Harrison discloses the therapeutic agent can be in various forms, such as a cream, ointment, foam, paste, gel for delivering a higher concentration to the muscle of the uterus for the treatment of dysmenorrhea (Abstract and col. 13, lines 34-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the various forms of the therapeutic agent of Lucas for the benefits disclosed in Harrison.

As to claims 21, 39, and 40, see Abstract and col. 13, lines 34-60.

As to claim 22, Harrison discloses the claimed therapeutic agents (col. 4, lines 43-59).

As to claims 43 and 62, Harrison discloses a mucoadhesive (col. 2, lines 60-63).

7. Claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb et al. USPN 3490454 in view of Lucas.

As to claims 1, 3, 28, 36, 42, 45, and 50, Goldfarb discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer and contacting the non-cornified epithelium. Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including an encapsulated therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14). However, Goldfarb does not specifically teach

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the therapeutic agent is a botanical. Lucas discloses a therapeutic agent comprising a botanical (grapefruit seed) used as a bactericide, fungicide (page 3, lines 15-17). It would have been obvious to modify the therapeutic agent of Goldfarb to include a botanical, since both Lucas and Goldfarb (col. 8, line 1) teach a bactericide and/or fungicide is desirable in the absorbent product.

As to claim 29, Goldfarb/Lucas disclose the therapeutic agent is released by pressure (Goldfarb col. 5, lines 1-5).

As to claim 5, Goldfarb/Lucas discloses the agent is located on an open or a gauze nonwoven, either of which is essentially an apertured web (Goldfarb col. 3, lines 53-54 and col. 4, lines 8-14).

As to claim 35, Goldfarb/Lucas discloses the therapeutic agent is applied to creped tissue, which is well known in the art as a biodegradable material (Goldfarb col. 3, lines 34-44).

As to claim 38, Goldfarb/Lucas discloses the therapeutic agent comprises a hydrogel (Goldfarb col. 6, lines 45-75).

As to claim 40, Goldfarb/Lucas discloses the therapeutic agent comprises a polymeric material (Goldfarb col. 8, lines 8-38).

As to claims 47 and 49, Goldfarb/Lucas discloses the agent is applied to various layers and between layers of the absorbent product (Goldfarb col. 3, lines 34-44 and col. 4, lines 8-10). Therefore, the agent is applied before the body is completed.

8. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lucas in view of Bowie et al. USPN 5585277. Lucas discloses the present invention substantially as claimed. However, Lucas does not disclose a ligand as part of the formulation. Bowie discloses ligands can be used therapeutically to bind a target protein associated with a condition or disease, preventing or treating a condition or disease, regulate physiological function, or serve as a lead compound for identification of a therapeutically useful compound (col. 1, lines 51-60). It would have been obvious to one having ordinary skill in the art to modify the therapeutic agent of Lucas with a ligand for the benefits disclosed in Bowie.

9. Claims 6, 8, 9, 16, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldfarb USPN 3490454 in view of Lucas and further in view of Karami et al. USPN 4726976.

Goldfarb/Lucas discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer. Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14). Goldfarb/Lucas discloses the agent is located on a porous nonwoven (Goldfarb col. 3, lines 53-54 and col. 4, lines 8-14). However,

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Goldfarb does not disclose the nonwoven is a hydrophobic polymer. Karami discloses a hydrophobic coversheet for the benefit of reducing rewet (Karami col. 6, lines 33-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb with a hydrophobic cover layer for the benefits disclosed in Karami.

As to claims 6, 8, and 16, Goldfarb/Lucas/Karami discloses the porous nonwoven sheet is polypropylene (Karami, Abstract).

As to claim 9, Goldfarb/Lucas/Karami discloses the agent is coated on the fibers (Goldfarb col. 4, lines 8-10).

As to claims 53, Goldfarb discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer and contacting the non-cornified epithelium. Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means, such as a cover sheet or within the body of the absorbent, for carrying a formulation including an encapsulated therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14). However, Goldfarb does not specifically teach the therapeutic agent is a botanical. Lucas discloses a therapeutic agent comprising a botanical (grapefruit seed) used as a bactericide, fungicide (page 3, lines 15-17). It would have been obvious to modify the therapeutic agent of Goldfarb to include a botanical, since both Lucas and Goldfarb (col. 8, line 1) teach a bactericide and/or fungicide is desirable in the absorbent product.

Goldfarb/Lucas discloses a catamenial product and method for producing the product, which is capable of being partially positioned within the vestibule of a wearer

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Goldfarb discloses a tampon product col. 2, lines comprising a fluid-absorbent body and means for carrying a formulation including a therapeutic agent (col. 2, lines 16-21; col. 3, lines 4-10; col. 4, lines 8-14). Goldfarb/Lucas discloses the agent is located on a porous nonwoven (Goldfarb col. 3, lines 53-54 and col. 4, lines 8-14). However, Goldfarb does not disclose the nonwoven is a hydrophobic polymer. Karami discloses a hydrophobic coversheet for the benefit of reducing rewet (Karami col. 6, lines 33-53). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb with a hydrophobic cover layer for the benefits disclosed in Karami.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F Stephens whose telephone number is (703) 308-8320. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on (703) 305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacqueline F Stephens
Examiner
Art Unit 3761



June 14, 2004